REMARKS

This amendment is in response to the Office Action, dated July 25, 2007. Claims 25-26 and 29-36 remain pending. No new matter has been added.

Claim Rejections – 35 USC § 103(a)

Examiner rejected claims 25-26 and 29-31 under 35 USC § 103(a) as allegedly unpatentable over Targan, et al. in view of Vasiliauskas, et al. and Landers, et al. Applicants respectfully traverse these rejections.

Examiner asserts that the Targan, et. al. reference teaches detecting the presence of anti-I2, ASCA and anti-OmpC IgA molecules in an antibiotic reactive clinical subtype of Crohn's Disease patients, and differs from the claimed invention only by the recitation of a step of determining the magnitude of three markers in the subject further comprising a step of performing quartile analysis of the magnitude of each marker. In response, Applicants respectfully submit that Targan, et al., in view of Vasiliauskas, et al. and Landers, et al., does not anticipate the present application. Applicants submit that Targan, et al. only teaches that patients with seroreactivity to bacterial components, namely the OmpC and I2 markers, might be more likely to achieve antibiotic-induced remission to Crohn's Disease as compared to those who do not have expression of such markers. As the described antibodies are known to be produced in response to components of specific bacteria, the Targan, et al. reference merely suggests that an appropriate antibiotic therapy for an individual might be determined through the detection of antibodies of a corresponding bacterial component. Like Targan, et al., the present invention pertains to the determination of anti-I2, ASCA and anti-OmpC IgA molecules; however, unlike the cited reference, the present invention describes these markers in relation to their associations with specific Crohn's Disease subgroups, such as fibrostenosis. The invention as claimed goes beyond merely suggesting that bacterial component antibodies OmpC and I2 can be used to determine candidates for antibiotic therapy, and instead describes seroreactivity, including also that of ASCA, that can be stratified into specific Crohn's Disease subgroups. One of skill in the art could

not make these same associations based only on the results described by the reference. Furthermore, the Targan, et al. reference itself does not conclusively determine a correlation between seroreactivity and the likelihood of success for a particular antibiotic therapy, noting that trials of a more diverse cohort with antibiotics alone are required to corroborate their preliminary findings. Applicants respectfully submit that the Targan, et al. reference is not citable prior art under §102(b), and thus the rejection under §103(a) should be removed.

New Matter – 35 USC § 112, first paragraph

Claims 25-26 and 29-36 stand rejected under 35 USC § 112, first paragraph as allegedly a New Matter rejection. Applicants respectfully traverse these rejections.

Examiner asserts that there is no support for the determination of anti-I2 antibodies, ASCA and OmpC together for the recited method. Further, Examiner asserts, there is no support for determining the magnitude of the markers. In response, Applicants submit that support for such a method is given throughout the specification. For example, on page 86, lines 1-29, the specification describes statistically significant associations between markers and distinct disease phenotypes, such as small bowel disease, fibrostenosis, internal perforating disease, and small bowel surgery. An association with Crohn's Disease clinical subtypes are described for each marker, both independently and in conjunction with one another, and Applicants respectfully submit that one of ordinary skill in the art would be readily able to use such data to determine whether an individual is susceptible to the aforementioned disease phenotypes. The determination of the magnitude of markers is also clearly described throughout the specification. For example, page 68, lines 27-30 defines I2 positive reactivity as reactivity greater than two standard deviations above the mean reactivity obtained with control (normal) sera. Similarly, positive reactivity is defined for ASCA on page 72, lines 7-14, and OmpC on page 75, lines 17-20. Applicants respectfully submit that the determination of anti-I2 antibodies, ASCA and OmpC together for the recited method does not constitute New Matter.

All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. If questions remain regarding this application, the Examiner is invited to contact the undersigned at (213) 633-6800.

Respectfully submitted,
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